NOV 1 4 2000

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K003308

1. **Submitter's Identification:**

Microlife Corporation
9F, 431 Rui Guang Road
Nei Hu,
Taipei 114
Taiwan, Republic of China

Date Summary Prepared:

October 16, 2000

2. **Name of the Device:**

Microlife Digital Infrared Ear Thermometer, Models IR1DA1, IR1DB1 and IR1DD1.

3. **Information for the 510(k) Cleared Device (Predicate Device):**

Microlife Digital Infrared Ear Thermometer, Model IR1DA1, K#000969

4. **Device Description:**

The Microlife Digital Infrared Ear Thermometer, Models IR1DA1, IR1DB1 and IR1DD1 are electronic thermometers using an infrared sensor (thermopile) to detect body temperature from the auditory canal. Their operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent surfaces.

The Microlife Digital Infrared Ear Thermometer, consists mainly of the five parts:

a) IR Thermopile Sensor

b) ASIC

c) E^2 PROM IC

d) LCD and Blacklight

e) Key "2, Buzzer" 1

5. Intended Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The Microlife Digital Infrared Ear Thermometers, Models IR1DA1, IR1DB1 and IR1DD1 are substantially equivalent to the original Microlife Digital Ear Thermometer, Model IR1DA1.

The new models IR1DA1, IR1DB1 and IR1DD1 have the same intended use and are similar in design to the 510(k) cleared device.

The IR1DA1, IR1DB1 and IR1DD1 are identical in functionality and performance with the only difference being the external shape of the devices, and PCB layout of the devices. The modifications to our original 510(k) cleared device, model IR1DA1, include performance specifications, ergonomics of the user interface, dimensional specifications and environmental specifications. The temperature measurements algorithm and its software codes of the modified devices remains unchanged. The fundamental scientific technology of the modified devices remains the same as that of the 510(k) cleared device. The Microlife devices (IR1DA1, IR1DB1 and IR1DD1) works with both a 1-second called a "normal" mode, as well as a 3-second "rock" mode.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes ASTM E1112, ASTM E1104 and ASTM E-1965-98, as well as IEC 60601-1 and IEC 60601-1-2 requirements.

Guidance documents included the "FDA Guidance On The Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers", "Deciding When to Submit a 510(k) for a Change to An Existing Devices", and, "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications".

8. Discussion of Clinical Tests Performed:

Controlled human clinical studies were not conducted for the Microlife Digital Infrared Ear Thermometer modified devices, as well as no low power test as clinical studies/low power testing were conducted for the original unmodified device and remain unchanged. Accuracy performance, reliability and EMC testing is only applicable.

9. Conclusions:

The Microlife Digital Infrared Ear Thermometer, Models IR1DA1, IRDB1 and IRDD1 have the same intended use and technological characteristics as the unmodified model IR1DA1. Moreover, verification and validation tests contained in this submission demonstrate that the modified portions maintained its original safety and effectiveness. These engineering changes do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2000

Microlife Corporation
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent for
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K003308
Trade Name: Mircolife Digital Infrared Ear Thermometer
Models IR1DA1, IR1DB1 and IR1DD1
Regulatory Class: II
Product Code: FLL
Dated: October 19, 2000
Received: October 23, 2000

Dear Ms. Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K003308

Device Name: Microlife Digital Infrared Ear Thermometer, Models IR1DA1, IR1DB1 and IR1DD1.

Indications For Use:

The device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **(Per 21 CFR 801.109)** **OR** **Over-The-Counter Use** X **(Optional Format 1-2-96)**

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003308